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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,718	09/22/2003	R. Stephen Brown	14453	4655

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EXAMINER

BULL, CHRISTOPHER

ART UNIT PAPER NUMBER

1655

DATE MAILED: 03/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/665,718	<b>Applicant(s)</b> BROWN ET AL.	
	<b>Examiner</b> Christopher Bull	<b>Art Unit</b> 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 February 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4 and 6-53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-4 and 6-53 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some    \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 1-4 and 6-53 are pending, as modified by the preliminary amendment filed on 17 Feb 2006, which also canceled Claim 5.

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4, 6-12 and 49-53, drawn to a method of detecting an organism using substrate (or product) fluorescence and a partitioning element, classified in class 435, subclass 31.
- II. Claims 13-23, drawn to an optical probe and apparatus, both with partitioning element for detecting a molecule, classified in class 385, subclass 12.
- III. Claims 24-35 and 36-41, drawn to a system and kit for detecting the presence of an organism by the fluorescence of an enzyme substrate or product observed within a partitioning element, classified in class 435, subclass 287.4.
- IV. Claims 42-48, drawn to a method of detecting a target species using antibody binding and a partitioning element, classified in class 435, subclass 7.92.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II, as well as I and III, are related as process of use and product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). For case (1), the method could be practiced with the probe/apparatus of Invention II, or the system of Invention III. For case (2), the probe/apparatus of invention II could be used as a pH sensor by adding fluorescein derivatives, or as an oxygen sensor by adding ruthenium complexes. Invention III to the system has separate utility as a standard fluorimeter, using higher concentrations of fluorescent materials which did not partition into the membrane (which would be particularly resistant to fouling by biological materials).

Inventions I and IV are directed to related methods. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, Invention IV requires an antibody that is not required of Inventions I. The enzyme of Inventions I must be derived from the organism detected, whereas that of Invention IV is added with the antibody and not related to the organisms detected. Thus, Invention IV is mutually exclusive with Invention I, is not an obvious variant, and has a different design.

Inventions II and III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed

Art Unit: 1655

does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the application contains combination claims reciting the subcombination specifically, and combination claims reciting the subcombination broadly. These latter claims are evidence that the combination as claimed does not require the particulars of the subcombination as claimed for patentability.

The subcombination is the Apparatus for detecting the fluorescence of a molecule, Claim 18, which requires the optical probe of Claim 13, an excitation source and a detector. The Optical Probe is also drawn to detecting the fluorescence of a molecule, using an optical waveguide and a partitioning element for the molecule such that fluorescence of the molecule is coupled into the waveguide. Since the Optical Probe is for detecting fluorescence, it implicitly has an excitation source and a detector, or it could not function. Therefore, the Optical Probe and the Apparatus are considered as drawn to the same subcombination.

The subcombination (i.e., the optical probe and the apparatus) is recited (Claims 13 and 18) by itself specifically, as well as specifically in one combination (i.e., the kit of Claim 36). However, the System (Claim 24) recites the partitioning element, the excitation source and the detector but not the optical waveguide. In so doing, the subcombination is recited broadly in this other combination (Claim 24). See the AB<sub>sp</sub>/AB<sub>br</sub>/B<sub>sp</sub> case in MPEP § 806.05(c) II (b). The subcombination has separate utility

Art Unit: 1655

such as a pH sensor based on fluorescein derivatives, or as an oxygen sensor using ruthenium complexes.

Inventions II and IV, as well as III and IV, are related as products and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). Again both are case are true. For case (1), either apparatus could be used with either method, and are therefore distinct. For case (2), the probe and apparatus of invention II could be used as a pH sensor by adding fluorescein derivatives, or as an oxygen sensor by adding ruthenium complexes, while Invention III has separate utility as a standard fluorimeter, and neither needs the antibody of Invention IV.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are

Art Unit: 1655

subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher Bull whose telephone number is (571) 272-1327. The examiner can normally be reached on 7:30-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1655

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Bull  
Patent Examiner  
Art Unit 1655

cb

  
TERRY MCKELVEY, PH.D.  
SUPERVISORY PATENT EXAMINER